K090201

510(k) Summary of Safety and Effectiveness

MAR 2 7 2009

510(k) Submitter: Streck
7002 South 109th Street
Omaha, NE 68128

Official Correspondent: Carol Thompson, Quality Assurance Manager
(402)-537-5213

Date Prepared: March 25, 2009

Name of Device:
Trade Name: UA-Cellular™ for IQ
Common Name: Urinalysis Control
Classification Name: Hematology quality control mixture (864.8625)

Predicate Device: Cell-Chex Auto (K053362) Manufactured by Streck

Description:
UA-Cellular for IQ is a urinalysis control which contains stabilized human red and white blood cells and other inert particles in a preservative medium. UA-Cellular for IQ is a urine control for the IRIS iQ® 200 analyzer. The product is packaged in plastic bottles containing 120ml. The closures are polypropylene screw caps with polyethylene liners. There are two different levels; level 1 and level 2. The bottles will be packaged in a box with the package insert / assay sheet. The product must be stored at 2 - 10° C.

Intended Use:
UA-Cellular for IQ is an assayed cellular urine control for evaluating the accuracy and precision of automated procedures that measure urinary sediment parameters.

Comparison to Predicate Device:

	Cell-Chex Auto (Predicate Product)	UA-Cellular for IQ
Intended Use Statement	Cell-Chex Auto is an assayed whole blood control for evaluating the accuracy and precision of hematology instruments that measure blood cell counts in patient body fluid samples.	UA-Cellular for IQ is an assayed cellular urine control for evaluating the accuracy and precision of automated procedures that measure urinary sediment parameters.
Open Vial Stability	30 days	Same
Closed Vial Stability	75 days	60 days
Reagents	Stabilized human red and white cells	Same stabilized human red and white cells combined with non-squamous simulated epithelial and crystal components
Storage Conditions	2 - 10°C	Same

Discussion of Tests and Test Results:
Three types of studies were conducted to establish performance of UA-Cellular for IQ. The three tests conducted were Run-to-Run Reproducibility, Open Vial Stability and Closed Vial Stability. All testing showed that UA-Cellular for IQ is consistently reproducible, substantially equivalent to the predicate product and stable for the shelf life claimed.

Conclusions Drawn From Tests:
UA-Cellular for IQ is an assayed cellular urine control for evaluating the accuracy and precision of automated procedures that measure urinary sediment parameters. It meets the claim of a 60 day closed vial, and a 30 day open vial stability and consistent run-to-run performance. Reproducibility studies and Closed Vial stability results confirm lot-to-lot consistency in the manufacture of UA-Cellular for IQ. Customers can be assured of a reliable quality control material that meets their expectations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Streck
c/o Kerrie Oetter
Quality Assurance Coordinator
7002 South 109th St.
Omaha, Nebraska 68128

Re: k090201
Trade/Device Name: UA-Cellular™ for IQ
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology Quality Control Mixture
Regulatory Class: II
Product Code: JPK
Dated: January 26, 2009
Received: January 27, 2009

Dear Ms. Oetter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on the labeling regulation, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240- 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For question regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR), please contact the Division of Surveillance Systems at 240-276-3464. You many obtain other general information on your responsibilities under the Act from the Division of Small Manufactuers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: **UA-Cellular™ for IQ**

Indication For Use:

UA-Cellular for IQ is an assayed cellular urine control for evaluating the accuracy and precision of automated procedures that measure urinary sediment parameters.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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